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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,501	12/31/2003	Mark S. Scheib	51644/AW/W112	1810

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CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,501	SCHEIB, MARK S.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-1-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Parent case now USPN 6,733,499. This must be amended into the specification section entitled "Cross-reference to related application". Currently the specification only lists the parent case application number (10/118,680).

The action is final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Specification neglects to disclose "the ablation assembly also having a generally straight distal region extending substantially tangentially to the generally circular curve of the main region". Although it might be obvious to the inventor as to the meaning of the phrase, it is not obvious to a third party reader. (The term "tangentially" is not found in the specification. Although verbatim claim language is not required in the specification, it's beneficial to apprehension when a

contextual word such as "tangential" is well defined somewhere in the Applicant's disclosure.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the ablation assembly also having a generally straight distal region extending substantially tangentially to the generally circular curve of the main region" found in claim 25 is indefinite because it's strongly contextual (generally, substantially, tangentially) and not well defined in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-16, 19-22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Stewart et al. (6,325,797).

Stewart discloses a method of ablating inner circumferences of pulmonary veins (PV) using a catheter (fig. 6; 132) with a circular ablation assembly (fig. 8; 190), shape memory material (Nitinol; col. 13:8-10), a cylindrical tip electrode (194), and a generally straight distal region (see figure 4a).

Claims 1-5, 8-16, 19-22 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Koblish (6,745,080).

Koblish discloses a method of ablating inner circumferences of pulmonary veins (pulmonary vein ostium) including rotation (col. 7:54-59, col. 8:57-62, col. 9:42 through col. 10:3, col. 10:43-49) in clockwise and counterclockwise manners corresponding to pushing and pulling using a catheter (fig. 19) with a circular ablation assembly (depicted figure 19), lumen (142, *inter alia*) and cylindrical tip electrodes (18).

Claims 1-5, 8-16, 19-22 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Bowe et al. (6,771,996).

Bowe discloses a method of ablating inner circumferences of pulmonary veins (PV) using a catheter (fig. 10b, 10c) with a circular ablation assembly (fig. 10b, 10c), shape memory material (Nitinol; col. 11:1-8), lumen (100) and a cylindrical tip electrode (112, figure 10c). Bowe discloses ablation of a circumferential band defined (col. 10:22-27) as a **continuous** line traced around a region of space and which starts and ends at substantially the same location. Bowe's embodiment in figure 8, as do many of the Stewart embodiments, depicts a **discontinuous** circular array of electrodes. The Office

respectfully posits that rotation of the Bowe embodiment in figure 8, as well as the many similar embodiments in Stewart, **requires** rotation in order to create ablation of a circumferential band (which is defined as **continuous**). The fact that Bowe does not expressly state rotation does not preclude this straightforward deduction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 17-20, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart in view of Bowe et al. (6,771,996).

Stewart neglects to disclose dimensions. However, superior parameters/dimensions concerning the curve of the ablation assembly (190, figure 8, *inter alia*) could be determined via routine experimentation in light of Stewart. Under the supposition that the Applicant has claimed superior parameters/dimensions, Stewart thereby makes obvious these limitations. Further, for a singular generally circular curve see figures 6 and 7. Specifically regarding claim 16, the Examiner contends that rotating the device creating a "second position" and subsequently ablating would have been an obvious method step. Most surgeries require surgeons to apply energy more than once and to apply that energy using different configurations/positions of the device. Rotation is obvious in light of the symmetrical lesion depicted in figures 6 and 7. Without rotation

of the Stewart ablation assembly, the symmetrical lesion is not feasible. This observation makes rotation obvious in order to create the lesion in figures 2c and 2d. Furthermore, the obvious rotating step can only be done clockwise or counterclockwise, which correspond to pulling or pushing the tip electrode. The optimal of the (only) two choices would be determined through routine experimentation. This is certainly no cognitive leap warranting patentability.

Obviating any need to take "Official Notice" another reference with analogous art expressly disclosing rotation is presented. Bowe 6,771,996 discloses ablation of a circumferential band defined (col. 10:22-27) as a **continuous** line traced around a region of space and which starts and ends at substantially the same location. Bowe's embodiment in figure 8, as do many of the Stewart embodiments, depicts a **discontinuous** circular array of electrodes. The Office respectfully posits that rotation of the Bowe embodiment in figure 8, as well as the many similar embodiments in Stewart, **requires** rotation in order to create ablation of a circumferential band (which is defined as **continuous**).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Stewart in view of Bowe by determining dimensions as well as method steps through routine experimentation. The motivation would be to create a symmetrical lesion seen in Stewart figures 2c and figures 2d, by rotating the device.

Response to Arguments

Applicant's arguments filed 3-6-06 have been fully considered but they are not persuasive. The Applicant argues three points throughout the amendment.

First, the prior art neglects to disclose contacting the **inner** circumference of a tubular region (pulmonary vein) as claimed and that instead the outer circumference of a tubular region (pulmonary vein) is disclosed. Although this argument appears accurate, it does not reflect reality. A common pattern in prosecution of surgical methods is often ineffective arguments that rely upon objective statements regarding the human anatomy (as opposed to man-made structures). For example, saying that Stewart (6,325,797) discloses placing the catheter assembly outside the pulmonary vein is an objective statement. It neglects to consider anatomical differences throughout a population resulting in more gradual transitions from the inner to the outer section of the pulmonary vein and different pulmonary vein sizes, the fact that the targeted pulmonary ostium extends into the pulmonary vein (and hence the inner circumference of a tubular region), and also that the border between the inside and outside of the pulmonary vein is not an objectively defined structure as evidenced by the cover figure in Koblish (6,745,080). How would one define inner and outer pulmonary vein regions in the cover figure of Koblish (also see figures 17 and 19)? Where is the border between the two regions? How does one define that border? The same questions can be asked with regards to Bowe (6,771,996) figures 10b and 10c, 13b, 13c and 15. It would not be appropriate to cancel rejections based upon an arbitrary designation of what is considered inner and outer of an anatomical region. The Office agrees that Stewart 6,325,797, figure 2c and figure 2d depict targeting around the pulmonary vein implying

targeting an outer region/circumference, however, Stewart in addition discloses numerous embodiments including those that can reach an "inner" circumference such as that in figure 3a. For these reasons, arguing that the prior art neglects to teach targeting an inner circumference is not effective.

Second, the Applicant argues that prior art neglects to disclose a generally straight distal region that extends "substantially tangentially to the generally circular curve of the main region. In response, the Office cannot locate the term "tangentially" in the specification. Looking at the drawings and the specification, one cannot determine what the Applicant is describing in the phrase, "the ablation assembly also having a generally straight distal region extending substantially tangentially to the generally circular curve of the main region". From what is provided in the specification as well as the commonly accepted definitions of the words that make up the phrase, the Office deduces this term to be anticipated by Stewart 6,325,797 (figure 5 116,126,124), Koblish 6,745,080 (cover figure, element 34) and Bowe 6,771,996 (figure 10c element 106).

Third, the Applicant argues no rotation of the catheters in Koblish and Bowe. As mentioned above, Koblish discloses rotation of a stylet, **which is part of the catheter.** Bowe strongly implies and makes obvious rotation. Bowe 6,771,996 discloses ablation of a circumferential band defined (col. 10:22-27) as a **continuous** line traced around a region of space and which starts and ends at substantially the same location. Bowe's embodiment in figure 8, as do many of the Stewart embodiments, depicts a **discontinuous** circular array of electrodes. The Office respectfully posits that rotation of

the Bowe embodiment in figure 8, as well as the many similar embodiments in Stewart, **requires** rotation in order to create ablation of a circumferential band (which is defined as **continuous**).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hall et al. (6,652,517), col. 2:50-55 discloses rotation of an ablation device with discontinuous electrodes as seen in Bowe figure 8 for a circumferential lesion.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 and 25-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,733,499. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims involve a method for pulmonary vein ablation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
May 6, 2006

Roy D. Gibson

ROY D. GIBSON
PRIMARY EXAMINER